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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/471,276 12/21/99 EDWARDS

J GENSET.025CP

EXAMINER

020995 HM22/0925
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ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/471,276

Applicant(s)

EDWARDS ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). Such sequence(s) is present in Figure 5, and elsewhere. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because such sequence is not listed in the paper copy and the computer readable form (CRF) of the Sequence Listing. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this Office action. A computer readable form of the Sequence Listing and a statement under 37 CFR 1.821(f) are required. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Note the attached Notice of Draftsperson's Patent Drawing Review. Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this

requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-2, 10, and 20-21, drawn to polynucleotides, expression vector, and host cells containing same, classified in Class 536, subclass 23.1 and 24.1; Class 435, subclasses 320.1, and 325 and 419. If this group is elected, then the below sequence election requirement also is required.
- II. Claim 3, drawn to polypeptides, classified in Class 530, subclasses 300 and 350. If this group is elected, then the below sequence election requirement also is required.
- III. Claims 4-6, drawn to method of making a cDNA, classified in Class 536, subclass 25.3. If this group is elected, then the below sequence election requirement also is required.
- IV. Claim 7, drawn to method of making a polypeptide, classified in Class 435, subclass 68.1. If this group is elected, then the below sequence election requirement also is required.
- V. Claims 8-9, drawn to DNA array, 435, subclass 6. If this group is elected, then the below sequence election requirement also is required.
- VI. Claim 11, drawn to an antibody, classified in Class 530, subclass 387.1. If this group is elected, then the below sequence election requirement also is required.

VII. Claim 12, drawn to computer readable medium, classified in Class 345, subclass 521. If this group is elected, then the below sequence election requirement also is required.

VIII. Claims 13-16, drawn to computer systems, classified in Class 702, subclass 127. If this group is elected, then the below sequence election requirement also is required.

IX. Claims 17-18, drawn to methods of comparing sequences, classified in Class 702, subclass 19. If this group is elected, then the below sequence election requirement also is required.

X. Claim 19, drawn to methods of identifying a feature in a sequence, classified in Class 702, subclass 20. If this group is elected, then the below sequence election requirement also is required.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted to only the elected sequence. Applicants are informed that the sequence election requirement is NOT a species election requirement.

The inventions are independent/distinct, each from the other because of the following reasons:

The inventions of Groups (I, III-V, IX-X), Group II, Group VI, Group VII and Group VIII are independent distinct inventions because they are directed to different chemical types or other subject matter regarding the critical limitations therein. For Groups(I, III-V, IX-X), the critical feature is nucleic acids; for Group II, the critical feature is a polypeptide; for Group VI, the critical feature is an antibody; for Group VII, the critical feature is a computer readable medium, and for Group VIII, the critical feature is a computer system. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Groups (I, III-V, IX-X), however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if they were examined together. Additionally, polynucleotides, polypeptides, antibodies and transgenic plants have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it

is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the five Groupings of (I, III-V, IX-X), II, VI, VII and VIII are independent and/or distinct invention types for restriction purposes.

The inventions of Groups I, III-V, and IX-X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Group III, which is directed to method of making a cDNA, Group IV, which is directed to method of making a polypeptide, etc. Alternatively, the nucleic acids of Group I can be used in antisense technologies, which is also a clearly distinct usage of such nucleic acids.

Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art and thus are usually published separately in the literature because of their recognized divergent subject matter, there would be undue search burden if they were examined together. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is further reminded that a fully responsive communication will comprise a proper election of a group, and sequences, as well as compliance with the sequence rules as set forth above. Examination cannot proceed without a complete response.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:


Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.


S. "Joe" Zhou, Ph.D.

Patent Examiner


ARDIN H. MARSCHEL
PRIMARY EXAMINER